Sterne Kessler
Goldstein Fox
ATTORNEYS AT LAW

Robert Greene Sterne
Edward J. Kessler
Jorge A. Goldstein
David K.S. Cornwell
Robert W. Esmond
Tracy-Gene G. Durkin
Michele A. Cimbala
Michael B. Ray
Robert E. Sokohl
Eric K. Steffe
Michael Q. Lee
Steven R. Ludwig
John M. Covert
Linda E. Alcorn
Robert C. Millonig
Lawrence B. Bugaisky
Donald J. Featherstone
Michael V. Messinger

Judith U. Kim
Timothy J. Shea, Jr.
Patrick E. Garrett
Jeffrey T. Helvey*
Heidi L. Kraus
Edward W. Yee
Albert L. Ferro*
Donald R. Banowit
Peter A. Jackman
Molly A. McCall
Teresa U. Medler
Jeffrey S. Weaver
Kendrick P. Patterson
Vincent L. Capuano
Albert J. Fasulo II*
Eldora Ellison Floyd
Thomas C. Fiala
Brian J. Del Buono

Virgil Lee Beaston*
Kimberly N. Reddick
Theodore A. Wood
Elizabeth J. Haanes
Bruce E. Chalker
Joseph S. Ostroff
Frank R. Cottingham
Christine M. Lhulier
Rae Lynn Prengaman
Jane Shershenovich*
Lawrence J. Carroll*
George S. Bardmesser
Daniel A. Klein*
Rodney G. Maze
Jason D. Eisenberg
Michael A. Specht*
Andrea J. Kamage
Tracy L. Muller*

Jon E. Wright*
LuAnne M. Yuricek*

Registered Patent Agents
Karen R. Markowicz
Nancy J. Leith
Ann E. Summerfield
Helene C. Carlson
Gaby L. Longsworth
Matthew J. Dowd
Aaron L. Schwartz
Angelique G. Uy
Boris A. Matvenko
Mary B. Tung
Katrina Y. Pei
Bryan L. Skelton
Robert A. Schwartzman
John J. Figueroa

Timothy A. Doyle*
Jennifer R. Mahalingappa
Teresa A. Colella
Jeffrey S. Lundgren
Gloria Y. Rutherford
H. Brian Gage

Senior Counsel
Samuel L. Fox
Kenneth C. Bass III
Lisa A. Dunner

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*Practice Limited to Federal Agencies

February 20, 2003

WRITER'S DIRECT NUMBER:
(202) 772-8619
INTERNET ADDRESS:
schwartz@skgf.com

Commissioner for Patents
Washington, D.C. 20231

Art Unit 1614

Re: U.S. Utility Patent Application
Appl. No. 09/674,733; § 371 Date: May 2, 2001
For: **Melanocortin 1 Receptor Selective Compounds**
Inventors: Szardenings *et al.*
Our Ref: 1085.0050000/RWE/ALS

Sir:

Transmitted herewith for appropriate action are the following documents:

1. First Supplemental Information Disclosure Statement;

2. Form PTO-1449 (8 sheets) and accompanying (22) references; and

3. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Aaron L. Schwartz
Agent for Applicants
Registration No. 48,181

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Enclosures

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No. 3759
Szardenings *et al.*	Art Unit: 1614
Appl. No. 09/674,733	Examiner: *To Be Assigned*
§ 371 Date: May 2, 2001	Atty. Docket: 1085.0050000/RWE/ALS
For: **Melanocortin 1 Receptor Selective Compounds**	

#8 J.Q. 4/9/03

First Supplemental Information Disclosure Statement

Commissioner for Patents
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this First Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Information Disclosure Statement filed on July 16, 2002 in connection with the above-captioned application. Copies of these documents are also provided.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not

be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This First Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Aaron L. Schwartz
Agent for Applicants
Registration No. 48,181

Date: Febmy 20, 2003

1100 New York Avenue, N.W.
Suite 600
Washington, D.C. 20005-3934
(202) 371-2600

SKGF_DC1:32656.1

FORM PTO-1449

FIRST SUPPLEMENTAL
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.	APPLICATION NO.
1085.0050000/RWE/ALS	09/674,733
APPLICANT: Szardenings *et al.*	
§ 371 Date: 05/02/01	GROUP 1614

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
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	AL						Yes No
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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR		
	AS		
	AT	1	Bagutti, C. *et al.*, "[^{111}In]-DTPA-Labeled Analogues of α-Melanocyte-Stimulating Hormone for Melanoma Targeting: Receptor Binding *In Vitro* and *In Vivo*," *Int. J. Cancer* 58:749-755, Wiley-Liss, Inc. (1994).

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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SKGF Rev. 1/95

FORM PTO-1449 FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1085.0050000/RWE/ALS	APPLICATION NO. 09/674,733
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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	2	Bhardwaj, R.S. *et al.*, "Pro-Opiomélanocortin-Derived Peptides Induce IL-10 Production in Human Monocytes," *J. Immunol.* 156:2517-2521, The American Association of Immunologists (1996).
	AS	2	Cone, R.D. *et al.*, "The Melanocortin Receptors: Agonists, Antagonists, and the Hormonal Control of Pigmentation," *Recent Prog. Horm. Res.* 51:287-317, The Endocrine Society (1996).
	AT	2	De Wied, D. and Jolles, J., "Neuropeptides Derived From Pro-Opiocortin: Behavioral, Physiological, and Neurochemical Effects," *Physiol. Rev.* 62:976-1059, The American Physiological Society (1982).

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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	3	Eberle, A.N., "Structure-Activity Relationships of the Melanotropins," in *The Melanotropins: Chemistry, Physiology and Mechanisms of Action*, Eberle, A.N., Ed., S. Karger Publishing, Basel, Switzerland, pp.333-379 (1988).
	AS	3	Gonindard, C. *et al.*, "The Administration of an α-MSH Analogue Reduces the Serum Release of IL-1α and TNFα Induced by the Injection of a Sublethal Dose of Lipopolysaccharides in the BALB/c Mouse," *Pigment Cell Res.* 9:148-153, Munksgaard (1996).
	AT	3	Gruber, K.A. and Callahan, M.F., "ACTH-(4-10) through γ-MSH: evidence for a new class of central autonomic nervous system-regulating peptides," *Am. J. Physiol.* 257:R681-R694, The American Physiological Society (1989).

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	4	Hartmeyer, M. *et al.*, "Human Dermal Microvascular Endothelial Cells Express the Melanocortin Receptor Type 1 and Produce Increased Levels of IL-8 upon Stimulation with α-Melanocyte-Stimulating Hormone," *J. Immunol.* *159*:1930-1937, The American Association of Immunologists (August 1997).
	AS	4	Hnatowich, M.R. *et al.*, "ACTH receptors in nervous tissue. High affinity binding-sequestration of [^{125}I][Phe^{2},Nle^{4}]ACTH 1-24 in homogenates and slices from rat brain," *Can. J. Physiol. Pharmacol.* *67*:568-576, National Research Council of Canada (1989).
	AT	4	Hol, E.M. *et al.*, "Protection by an $ACTH_{4-9}$ Analogue Against the Toxic Effects of Cisplatin and Taxol on Sensory Neurons and Glial Cells In Vitro," *J. Neurosci. Res.* *39*:178-185, Wiley-Liss, Inc. (1994).

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	AR	5	Hruby, V.J. *et al.*, "Cyclic Lactam α-Melanotropin Analogues of Ac-Nle^4-cyclo[Asp^5,D-Phe^7,Lys^{10}] α-Melanocyte-Stimulating Hormone-(4-10)-NH_2 with Bulky Aromatic Amino Acids at Position 7 Show High Antagonist Potency and Selectivity at Specific Melanocortin Receptors," *J. Med. Chem.* *38*:3454-3461, American Chemical Society (1995).
	AS	5	Klein, M.C. *et al.*, "Pressor and Cardioaccelerator Effects of Gamma MSH and Related Peptides," *Life Sci.* *36*:769-775, Pergamon Press (1985).
	AT	5	Knittel, J.J. *et al.*, "Structure-Activity Studies of Highly Potent Cyclic [Cys^4,Cys^{10}]Melanotropin Analogues," *J. Med. Chem.* *26*:125-129, American Chemical Society (1983).

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	AR	6	Lichtensteiger, W. *et al.*, "Pre- and Postnatal Ontogeny of [^{125}I]Nle^{4},D-Phe^{7}-α-MSH Binding Sites in Rat Brain," *Ann. N.Y. Acad. Sci. 680*:652-654, New York Academy of Sciences (1993).
	AS	6	Lin, S.-Y., *et al.* "A γ-Melanocyte Stimulating Hormone-like Peptide Causes Reflex Natriuresis After Acute Unilateral Nephrectomy," *Hypertension 10*:619-627, American Heart Association (1987).
	AT	6	Murphy, J.R. *et al.*, "Genetic construction, expression and melanoma-selective cytotoxicity of a diphtheria toxin-related α-melanocyte-stimulating hormone fusion protein," *Proc. Natl. Acad. Sci. USA 83*:8258-8262, National Academy of Sciences (1986).

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	7	Prusis, P. *et al.*, "A Three Dimensional Model for the Interaction of MSH with the Melanocortin-1 Receptor," *Biochem. Biophys. Res. Commun. 210*:205-210, Academic Press, Inc. (1995).
	AS	7	Sawyer, T.K. *et al.*, "4-Norleucine, 7-D-phenylalanine-α-melanocyte-stimulating hormone: A highly potent α-melanotropin with ultralong biological activity," *Proc. Natl. Acad. Sci. USA* 77:5754-5758, National Academy of Sciences (1980).
	AT	7	Sawyer, T.K. *et al.*, "[half-Cys^4,half-Cys^{10}]-α-Melanocyte-stimulating hormone: A cyclic α-melanotropin exhibiting superagonist biological activity," *Proc. Natl. Acad. Sci. USA 79*:1751-1755, National Academy of Sciences (1982).

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	8	Tatro, J.B. *et al.*, "Interaction of an α-Melanocyte-stimulating Hormone-Diphtheria Toxin Fusion Protein with Melanotropin Receptors in Human Melanoma Metastases," *Canc. Res.* 52:2545-2548, American Association for Cancer Research (1992).
	AS	8	Thielemans, K.M.M., "Immunotherapy with Bispecific Antibodies," *Verh. K. Acad. Geneeskd. Belg.* 57:229-248, Paleis Der Academein (1995).
	AT	8	Wiegant, V.M. *et al.*, "Intracerebroventricular ACTH Activates the Pituitary-Adrenal System:Dissociation from a Behavioral Response," *Life Sci. 25*:1791-1796, Pergamon Press (1979).

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